DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAY 25 1999

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Frederick C. Kentz, III, Esq.
Vice President, General Counsel
Hoffman-LaRoche Inc.
340 Kingsland Street
Nutley, NJ 07110-1199

Re: Docket No. 98P-1075/CP1

Dear Mr. Kentz:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition submitted on November 27, 1998, requesting that the Agency take the following steps: (1) impose on any abbreviated new drug application (ANDA) for ticlopidine hydrochloride tablets a postmarketing safety program to include patient and professional education, as well as free blood monitoring, or (2) require you to submit a supplement to the Ticlid new drug application to incorporate the postmarketing safety program as a condition of use, allowing FDA to impose the program on ANDA applicants.

The Agency is still evaluating the requests made in your petition, and we will respond to your petition once this process is completed. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely yours,

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research

98P-1075

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